K071438 **510 (k) Summary of Safety and Effectiveness**

Date Summary Prepared: August 17, 2007

AUG 21 2007

Submitter Information: Spinal USA
644 Lakeland East Drive Suite A
Flowood, MS 39232

Contact Name: Jeffrey Johnson
Phone: 601-420-4244
Fax: 601-420-5501
E-mail: jeff@spinalusa.com

Device Trade Name: PSS System

Common Name: Pedicle Screw Spinal System
MNH (Class II) 888.3070(b)(1)
MNI (Class II) 888.3070(b)(1)

INTENDED USE:
The PSS System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The PSS System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4 of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudoarthrosis; and failed previous fusion.

DEVICE DESCRIPTION:
The PSS System is a top-loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, locking cap screws. All of the components are available in a variety of sizes to match more closely the patient's anatomy. All components are made from medical grade titanium or titanium alloy described by such standards as ASTM F136 or ISO5832-3. The products are supplied clean and "NON-STERILE".

EQUIVALENT DEVICE:
Testing in accordance with ASTM F171 7 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model" of the PSS System demonstrates that the device is substantially equivalent to the Moss Miami Pedicle Fixation System (K980447), Optima Spine System (K031585), and the Xia Spinal System (K984251).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2007

Spinal USA
% Mr. Jeffrey Johnson
Manager, Regulatory Affairs
644 Lakeland East Drive, Suite A
Flowood, Mississippi 39232

Re: K071438
Trade/Device Name: PSS System
Regulation Number: 21 CFR 888.3070(b)(1)
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: II
Product Codes: MNI, MNH
Dated: May 22, 2007
Received: May 23, 2007

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This

letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devicesd
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071438

Device Name: PSS System

Indications for Use:

The PSS System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The PSS System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4 of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudoarthrosis; and failed previous fusion.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K071438